IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DISVISION AT COOKEVILLE

ANDREW SCOTT RODRIGUEZ, Plaintiff, vs. STRYKER CORPORATION, a Michigan Corporation; STRYKER SALES CORPORATION, a Michigan corporation, Defendants.	C.A. No. 2:08-cv-124 JUDGE ALETA A. TRAUGER MAGISTRATE BRYANT JURY DEMAND

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO EXCLUDE SUZANNE PARISIAN, M.D.

Pursuant to Rule 702 of the Federal Rules of Civil Procedure, Defendants Stryker Corporation and Stryker Sales Corporation (collectively "Stryker") file this Memorandum in Support of Defendant's Motion to Exclude Suzanne Parisian, M.D., and state the following in support:

I. SUMMARY OF ARGUMENT

It is rare when a court has the luxury of assessing the relevance and reliability of an expert with the aid of other courts, which have evaluated the same expert in various contexts and occasions. As to Dr. Suzanne Parisian, this Court treads a well-worn path. She has been weighed and found wanting time and again by courts who have concluded that she is a transparent advocate, retained to give voice to the plaintiffs' closing arguments.

Dr. Parisian's deficiencies are legion, but ultimately revolve around the same phenomenon: she regurgitates FDA regulations and defendants' internal documents and testimony in a narrative that contains no expert analysis and frequently is unconnected to her

claimed regulatory expertise. Not surprising, that is the same course she has taken with her opinion in this case. Dr. Parisian gives a lengthy report outlining various federal regulations, and the regulatory and development history of Stryker's pain pump with bold statements of liability and causation but with no analysis. Dr. Parisian, as self-imposed regulatory czar for Stryker pain pumps, lists various federal regulations that Stryker has allegedly violated as a "responsible manufacturer." Although she states in her deposition in this litigation that she is not going to opine at trial that Stryker "violated a particular FDA statute," (June 4, 2010 Parisian deposition at 34:14-35:7, attached as **Exhibit A**) she does just that by listing the various regulations that Stryker has "failed" to comply with or "deviated from." Expert Report of Suzanne Parisian, M.D. ("Parisian Rpt.") at 5-6, attached as **Exhibit B**. This offered testimony is irrelevant in the jury's consideration of Stryker's liability under Tennessee law. It is in conflict with the U.S. Supreme Court's holding that it is constitutionally impermissible for a jury to impose state law liability on a pharmaceutical manufacturer based on violations of federal regulations and further serves to confuse and prejudice Stryker to the jury. *Buckman Co. v. Plaintiff's Legal* Committee, 531 U.S. 341, 348 (2001). Moreover, the "facts" used to support Dr. Parisian's opinion post-date the alleged injury in this case and are therefore even further irrelevant.

The central point of her unabashed critique of Stryker is that through violations of regulatory requirements, Stryker did not adequately inform physicians of the risks associated with its device. The kind of testimony that Dr. Parisian would like to offer on federal regulatory compliance flies in the face of established precedent under *Buckman*, and Tennessee law. Moreover, even if the law was not clear on that point, the facts that support Dr. Parisian's opinion that Stryker was noncompliant with federal regulations are wanting by her own admission. Dr. Parisian testified in her deposition in this litigation that the FDA has taken no

regulatory enforcement action against Stryker, she knows of no regulatory or statutory violation by Stryker that has rendered the anesthetics used in its pumps as misbranded, and that Stryker had no obligation to amend its labeling to advise surgeons of FDA regulatory actions. And, most importantly, the treating physician in this case was very emphatic at his deposition that he did not rely on any label or admission from Stryker in using the pain pump in his treatment of Plaintiff.

Besides the impermissible, irrelevant, and unreliable testimony offered by Dr. Parisian, she lacks the qualifications to opine on this particular device, which is consistent with findings by other courts. Here, she has no experience in the regulation of pain pumps, and yet is prepared to articulate a host of opinions, all of which are premised on this supposed experience.

Given Dr. Parisian's vast experience as a plaintiffs' expert, many other courts have had the opportunity to wrestle with her proposed testimony. Some courts have allowed her to testify under strict constraints but Dr. Parisian has proven that she cannot be confined—releasing the full spectrum of her improper opinions despite courts' limitations. Recently, however, she has encountered courts that have seen through her gambit and simply refused to be fooled, excluding her testimony entirely. This Court should do likewise.

The table below sets forth a summary of Dr. Parisian's opinions (Parisian Rpt. at 5-6 and *generally* therein) and Stryker's objections. The following sections provide an in-depth analysis of these challenges to both the relevancy and reliability of her opinions in this case.

OPINION #1: Stryker deviated from conduct of a responsible United States medical device manufacturer when it promoted postoperative pain pumps for new and unapproved orthopedic surgery indications, including continuous intra-articular infusion of a local anesthetic, without having first obtained the necessary FDA approval, conducted adequate	• Fails to satisfy Rule 702 or *Daubert*; • Has no relevance or "fit" under *Daubert;* • Lacks foundation generally; • Lacks foundation as to whether Stryker

testing or investigation, failed to provide physicians with adequate instructions for use or warnings. (21 USC § 331(a); 21 USC § 360c; 21 USC § 351; 21 CFR § 807; 21 USC § 352(f)(1),(2); 21 USC § 321(n))	promoted postoperative pain pumps "for new and unapproved orthopedic surgery indications," and relevancy to Dr. John Kuhn's treatment of plaintiff and plaintiff's alleged injuries; • Lacks foundation as to whether "Stryker deviated from conduct of a responsible . . . manufacturer;" • Improperly expresses legal conclusions as to what was "responsible," "necessary," and "adequate" under applicable law and regulations; • Speculative; and • Fails to comply with Rule 26(a)'s requirement of "a complete statement of all opinions the witness will express and the basis and reasons for them" by not fully disclosing "new and unapproved orthopedic surgery indications."
OPINION #2: Stryker's promotion and advertising of its postoperative pain pumps as safe and effective for unapproved intra-articular infusion of local anesthetics misbranded other pharmaceutical manufacturers' products pursuant to 21 CFR §801.6 (Also 21 §201.6). Such conduct is prohibited by the Food, Drug and Cosmetic Act. (21 USC § 331; 21 CFR § 801.4; 21 CFR § 201.6; 21 CFR § 801.6; 21 CFR § 201.128)	• Fails to satisfy Rule 702 or *Daubert*; • Has no relevance or "fit" under *Daubert;* • Lacks foundation generally; • Lacks foundation as to whether Stryker promoted or advertised "its postoperative pain pumps as safe and effective for unapproved intra-articular infusion of local anesthetics;" • Improperly expresses legal conclusions generally, and specifically, as to whether a product is "misbranded," or whether conduct was legally "prohibited;" • Speculative; and • Fails to comply with Rule 26(a)'s

	requirement of "a complete statement of all opinions the witness will express and the basis and reasons for them" by not fully disclosing her opinion on the "misbranding of other pharmaceutical manufacturers' products."
OPINION #3: Stryker failed to inform and warn physicians that it had not studied or tested the safety of post operative intra-articular continuous infusion with a local anesthetic. (21 USC § 331; 21 CFR § 812; 21 USC § 352(f)(1),(2); 21 CFR § 1.21)	• Fails to satisfy Rule 702 or *Daubert*; and • Has no relevance or "fit" under *Daubert;* • Improperly expresses a legal conclusion in stating Stryker "failed;" and • Speculative.
OPINION #4: Stryker failed to adequately monitor and warn physicians and FDA about risks associated with postoperative continuous intra-articular infusion. Stryker also did not inform physicians there was no local anesthetic approved for that new indication. (21 CFR § 820; 21 CFR § 803; 21 CFR § 801.109; 21 USC § 352(f)(1),(2))	• Fails to satisfy Rule 702 or *Daubert*; • Has no relevance or "fit" under *Daubert* generally and specifically to this plaintiff because purported risks were not known until following Plaintiff's surgery; • Speculative; • Vague and ambiguous with respect to "safety signals;" • Lacks foundation generally; • Lacks foundation as to whether Stryker monitored and warned physicians and the FDA about risks associated with postoperative continuous intra-articular infusion; and • Improperly expresses legal conclusions as to Stryker "failed" and what was "adequate."

II. LEGAL AUTHORITY

Before an expert can express an opinion, the following factors must be satisfied: (1) the expert must seek to testify regarding "scientific, technical, or other specialized knowledge;" (2) the expert must be qualified to express an opinion on the topic; (3) the expert's opinion must be relevant; (4) the expert's opinion must be reliable; and (5) the proffered testimony must be "otherwise admissible." *See* Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The U.S. Supreme Court directed trial courts to serve as "gatekeepers" to ensure that, consistent with Rule 702, "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. Although *Daubert* focused specifically on "scientific" testimony, the Supreme Court has made it clear that *all* expert testimony must meet the rigors articulated in that case. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

Daubert's progeny have made it clear that in performing the inquiry into admissibility of an expert's testimony, a court should assess the relevancy requirement by determining whether there is a "fit" between the testimony and the issues to be resolved in the case. *See United States v.* Bonds, 12 F.3d 540, 555 (6th Cir. 1993). As to reliability or the foundational requirements of an expert's proffered testimony, the focus should be on the methodology and principles underlying the testimony. *Id.* at 556; *Greenwell v. Boatwright*, 184 F.3d 492, 495-496 (6th Cir. 1999).

III. LEGAL AUTHORITY CONCERNING DR. PARISIAN

Because Dr. Parisian is so well traveled as an expert for hire, courts around the country have weighed in on the admissibility of her opinions under Rule 702 and *Daubert*. Below is a brief synopsis of pertinent authorities:

***Reece v. AstraZeneca Pharms., LP*, 500 F. Supp. 2d 736, 741-46 (S.D. Ohio 2007).**

- Court found it "clear … that Dr. Parisian seeks to offer testimony and opinions on matters that go well beyond FDA procedures and regulations and her areas of expertise." *Id*. at 744.

- Parisian prohibited from testifying regarding medical causation and failure to warn due to invalid methodology and reasoning, which rendered her testimony unreliable and unhelpful. *Id*. at 744-46.

- Parisian permitted to testify only concerning limited areas of FDA regulations and processes and manufacturer's responsibility within that system. *Id*. at 744.

***In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 2007 WL 1964337 at *7-*8 (D. Minn. June 29, 2007), attached at Exhibit C.**

- Parisian prohibited from testifying regarding:
  - whether the FDA approved a use under FRE 702 and Daubert. *Id*. at *7.
  - what use the FDA approved for lack of foundation. *Id*. at *7.
  - whether the manufacturer "violated" or "failed" obligation to warn. *Id*. at *7.
  - the manufacturer's knowledge. *Id*. at *8.
  - whether the manufacturer "violated" FDA conditions of approval. *Id*. at *8.
  - whether the manufacturer conduct was "ethical." *Id*. at *8.

- Parisian permitted to testify only to regulatory process, FDA expectations, and whether the manufacturer's actions were reasonable. *Id*. at *7.

***In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 665-71 (D.N.J. 2008).**

- Parisian prohibited from testifying to general causation because:
  - "At no point during either her affidavit or deposition did Dr. Parisian adequately explain how her conclusions could be extrapolated from the results or conclusions of any of the studies [she cited]." *Id*. at 666.
  - "Her explanations of the other referenced studies were similarly unhelpful." *Id*. at 666.
  - "Dr. Parisian's extrapolations from those studies to her ultimate conclusion lack the factors of reliability." *Id*. at 667.
  - "At best, her opinion from these studies is nothing more than pure speculation." *Id*. at 667.

- "Dr. Parisian's lack of professional experience and knowledge of the question … at issue is telling." *Id*. at 668.

***In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 189-92 (S.D.N.Y. 2009).**

- Parisian prohibited from testifying to failure of adequate disclosure because "she could not name any standard that prohibits such a practice," thus her opinion was "too conclusory or insufficiently based on expertise or analysis to be admitted." *Id*. at 191.

- Parisian prohibited from presenting "a narrative of select regulatory events through the summary or selective quotation from internal Merck documents, regulatory filings, and the deposition testimony of Merck employees." *Id*. at 192.

- Parisian "not permitted to merely read, selectively quote from, or 'regurgitate' the evidence." *Id*. at 192.

- Parisian prohibited "from testifying as to the knowledge, motivations, intent, state of mind, or purposes of Merck, its employees, the FDA, or FDA officials …. Dr. Parisian conceded at the hearing that her regulatory expertise does not give her the ability to read minds. Nevertheless, her report is replete with such conjecture. This is not a proper subject for expert or even lay testimony." *Id*. at 192.

- Parisian prohibited from providing "bad company testimony." *Id*. at 192.

Recent cases indicate, however, that the judiciary's patience with Dr. Parisian has run out:

***In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009).**

- District court's post-trial striking of much of Parisian's testimony and related exhibits upheld on appeal because "[t]he record reflects that often Dr. Parisian simply read the contents of exhibits, thus undermining the asserted basis for expert testimony. At a sidebar conference during the testimony, the district court instructed [plaintiff's] counsel to relate the testimony to FDA guidelines; nevertheless, the testimony continued in the same manner." *Id*. at 571.

***In re Trasylol*, 709 F.Supp. 2d 1323 (S.D. Fla. 2010).**

- Parisian excluded entirely because "[p]lainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her 'takeaway' or 'take home message' with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise." *Id*. at 1351.

A recent decision from a Canadian court regarding the admissibility of Dr. Parisian's purported expert opinions regarding regulatory compliance illustrates (a) that she is indiscriminate in the expert witness assignments she is willing to undertake, (b) she lacks qualifications to opine on most of the topics on which she proposes to testify, and (c) her opinions generally far outstrip whatever expertise she possesses. *Anderson v. St. Jude Medical, Inc.*, Court file no. 00-CV-195906CP, Ontario, Superior Court of Justice, involved a contention that defendants made false representations to regulators concerning the safe and efficacy of a mechanical heart valve. *See* Justice Lax's March 3, 2010 Order excluding Dr. Parisian attached as **Exhibit D**. Plaintiffs offered Dr. Parisian for opinion evidence on FDA practices in approving a medical device, including manufacturer disclosures, required investigations, and whether defendant fulfilled its obligations in the pre and post approval process. *Id.* at 467-468.

On defendants' objection, Dr. Parisian was excluded as an expert witness. Justice Lax noted that Dr. Parisian's FDA service was in a different office of the FDA that did not regulate heart valves (and likewise in this action, Dr. Parisian's assignment in the Division of Reproductive, Abdominal, Ear, Nose & Throat, and Radiology, did not oversee pain pumps). *Id.* at 469-470. As with pain pumps, she had no knowledge or experience relevant to heart valves that "would inform the practices and procedures of the FDA in approving this kind of device." *Id.* at 472. Thus, she was found unqualified as to heart valves, and whatever expertise she had with respect to other devices was found to be unhelpful. *Id.* at 474.

Turning to post-approval regulatory compliance, Justice Lax also excluded Dr. Parisian's testimony. With respect to her opinions that the defendants breached FDA regulations, Her Honor ruled she was not qualified to do so:

> Dr. Parisian is not a lawyer and her role at FDA did not entail providing legal opinions, but rather providing her clinical

> perspective on public safety issues in instances of alleged non-compliance. She is not qualified to provide expert evidence to assist the court with proving the content of U.S. law or opinion on the interpretation of these laws so as to conclude that St. Jude was in violation of the U.S. FDCA regulations and/or FDA's conditions of approval.

Id. at 476-477. Of course, this is precisely the subject—breach of applicable regulations—on which Dr. Parisian purports to testify in this Court.

In sum, Justice Lax ruled Dr. Parisian was not qualified to opinion on either regulatory violations or what regulators would have done had there been regulatory compliance under her construction of the regulatory scheme. *Id.* 481-482. "She is also not qualified to testify about U.S. regulatory law, ..." *Id.* at 482. This is exactly what, in essence, Plaintiff proposes Dr. Parisian should testify about in this case. She should be excluded here as she was in the Canadian court.

IV. ARGUMENT

A. Dr. Parisian's Opinion on Purported FDA Regulation Violations and Legal Conclusions are Irrelevant, Legally Improper, and Confusing to the Jury.

Dr. Parisian's proffered opinion is laden with allegations of federal regulation violations and legal conclusions which are not only improper but irrelevant under *Daubert*. Even though the FDA has never taken any action or imposed any changes to Stryker's device labeling to date, Dr. Parisian has taken it upon herself to be a private-citizen FDA compliance officer as to Stryker's product. In doing so, she basically implies that she can do it better than the FDA officials overseeing the approval and post-marketing surveillance of Stryker's pain pump. Her opinion and legal conclusions puts her in a position as FDA, judge and jury. *See Torres v. County of Oakland*, 758 F.2d 147, 150 (6th Cir. 1985) ("This 'invade[s] the province of the court to determine the applicable law and to instruct the jury as to that law.'") (citations omitted).

However, the proffered testimony and evidence has been squarely overruled by the U.S. Supreme Court. In *Buckman*, the Court held that the FDA has exclusive jurisdiction to determine whether medical device manufacturers have failed to comply with federal regulations. *See Buckman*, 531 U.S. at 349 n.4 ("The [Food, Drug and Cosmetics Act] leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . .").

Tennessee courts have come down consistently with the *Buckman* decision. As such, they have ruled that FDA regulatory evidence is irrelevant to Tennessee product liability causes of action:

> In the instant cases, the plaintiffs are required to prove that the fixation devices were defective or unreasonably dangerous at the time they left the manufacturer's control. It appears from our review of the record that the evidence excluded by the trial court and offered in proof does not tend to prove the determinative issues in the case nor lead to evidence that would prove such issues. The FDA's approval or nonapproval of the devices without more does not tend to prove that the devices were defective or unreasonably dangerous.

Bish v. Smith & Nephew Richards, Inc., 2000 WL 1294324, *5 (Tenn. Ct. App. Aug. 23, 2000) (emphasis added), attached as **Exhibit E**; *see also King v. Danek Medical, Inc.*, 37 S.W.3d 429, 457 (Tenn. Ct. App. 2000) (holding that testimony about FDA regulations is irrelevant as to standard of care).

Indeed, the unanimous *Bish* Court unequivocally held that the resulting prejudice and confusion from testimony about alleged FDA violations would easily outweigh the probative value of the testimony:

> Moreover, a review of the testimony of the three witnesses offered by plaintiff Burton aptly illustrates the reason for Tenn. R. Evid. 403. The introduction of the proof concerning the FDA activity in regulation would result in a confusion of the issues, could mislead

> the jury, and without question would result in undue delay and a waste of time. Under the state of this record, if there is any probative value to the testimony, it is substantially outweighed by the dangers outlined in Rule 403.

Bish, 2000 WL 1294324, at *5.

At the federal level, court after court has recognized that private parties cannot enforce the FDCA—particularly its prohibitions on "misbranded." devices. *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, -- F.3d --, 2010 WL 4026802, *2 (8th Cir. Oct. 15, 2010) (only the United States may enforce "FDA requirements"); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994) (citing cases); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008) ("[P]laintiff … cannot escape preemption by reference to provisions of the FDCA that govern the sale of adulterated and misbranded devices because there is no private right of action under the FDCA.") (emphasis added); *Lewkut v. Stryker Corp.*, -- F. Supp. 2d --, 2010 WL 1544275, *8 (S.D. Tex. April 16, 2010) ("[T]he statutory language of the FDCA, as well as case law, makes clear that the provisions of the FDCA, including that which establishes and defines the prohibition on 'adulterated devices', are to be enforced through the United States government only.") (emphasis added).

Ultimately, Plaintiff is attempting to use Dr. Parsian's testimony to enforce laws that she has no business enforcing. *See id*. ("[C]ourts have held that that private enforcement of FDCA regulations via state common law would interfere with this regulatory scheme and is therefore prohibited.") (citing *Buckman*); s*ee also Mass v. McDonald's Corp.*, 2004 WL 2624255, *3 (N.D. Tex. Nov 12, 2004) ("The FDCA . . . vests enforcement authority exclusively in the federal government."), attached as **Exhibit F**. This Court should give proper deference to the FDA and take action as others courts have done in excluding Dr. Parisian from offering testimony regarding purported FDA violations.

i. Dr. Parisian's Own Testimony Debunks her Position on Stryker's Regulatory Compliance.

Although the law is clear that Dr. Parisian's proffered testimony is impermissible, her allegations that Stryker violated certain FDA regulations is not supported by the evidence or even her testimony in this litigation. The overarching theme of Dr. Parisian's report is that as a consequence of Stryker's violations of FDA regulatory requirements physicians were not given "adequate instructions on use or warnings." Parisian Rpt. at 5. However, her deposition in this litigation, taken on June 4, 2010, belies this dominant theme:

- In response to a question asking her to identify laws or regulations that Stryker violated that rendered a drug company's product mislabeled, Dr. Parisian answered "I'm not here to say that Stryker violated ***any*** law." June 4, 2010 Parisian deposition 128:10-21, emphasis added.

- She admitted that the FDA has ***never*** moved against Stryker or any other pain pump manufacturer requesting in any fashion that the labeling for the cleared indication for use be altered or changed. *Id.* at 47:19-25.

- She agreed that by the end of 2004 (at the time of Plaintiff's surgery), Stryker had received neither reports nor complaints regarding potential cartilage injury from use of its pain pumps. *Id.* at 106:22-107:22.

- She is unaware of ***any*** Stryker document indicating improper promotion of "off-label" use of pain pumps (such as for glenohumeral catheter placement). *Id.* at 173:18-24.

- Despite all the recent publicity about continuous infusion therapy, she testified that the FDA ***never*** invoked its enforcement powers to require Stryker to modify its pain pump labels. *Id.* at 26:8-13.

- She agreed that Stryker had ***no*** obligation to include in its pain pump labeling any statement to the effect that the FDA had removed a previously cleared indication for use. *Id.* at 36:24-37:7.

How, in light of these concessions, can Dr. Parisian plausibly assert that there have been any purported regulatory transgressions, particularly since the FDA has taken absolutely no action against Stryker? The answer is plainly that she cannot.

ii. The Treating Physician's Testimony is What is Relevant Under Tennessee Law.

Moreover, the relevant issue here, in contrast to Dr. Parisian's baseless assertions of regulatory noncompliance, is the adequacy of Stryker's warning under Tennessee law. *See Bish*, 2000 WL 1294324, at *5. But, ironically, any testimony about the adequacy of the warning is irrelevant in *this* case—because there is no evidence that the treating orthopedic surgeon, Dr. John Kuhn, read the relevant warnings. *See* Deposition of Dr. John E. Kuhn at 55, attached as **Exhibit G** ("Q. First, as you sit here today, do you recall reviewing Stryker's instructions for use? A. I don't recall it.").

Indeed, every aspect of Dr. Kuhn's decision to prescribe a pain pump to Plaintiff was based on his training, experience, and course of practice, not any communication from Stryker. He had been using pain pumps for years. Stryker pumps were the ones he predominantly used at Vanderbilt, and they were also among the ones he had used in his prior position with the University of Michigan (when he was there from 1994 to 2004). *See id*. at 13-14. Specifically, his initial decision to use pain pumps and his determination of their indications and contraindications was driven, not by any information from the manufacturer, but rather by the medical literature. *Id*. at 62:5-63:6, 21:1-16. Dr. Kuhn established his protocol for using pain pumps while at Michigan, and did not change it thereafter, even after his arrival at Vanderbilt in 2004. *Id*. at 13:22-14:20.

Of course, when Dr. Kuhn first starts to use a new product, he generally looks at the literature from the manufacturer. *Id*. at 63; *see also id*. at 57. But in this case, Dr. Kuhn's possible review of the warnings from the 1990s would be irrelevant. The only relevant issue is whether Dr. Kuhn would have reviewed the updated warnings that Plaintiff proposes in November 2004. The answer to that is no. *See id*. at 55 (Dr. Kuhn does not recall reviewing the

relevant "instructions for use"). In fact, Dr. Kuhn does not normally review the "instructions for use" unless he is unfamiliar with the device. *See id*. at 55. Clearly, Dr. Kuhn was familiar with Stryker's pain pumps by November 2004. *See id*. at 13-15 (indicating that Dr. Kuhn had performed 350 shoulder surgeries a year back when he was in Michigan).

In summary, there is no evidence that Dr. Kuhn would have ever read an updated warning from Stryker—while there is affirmative evidence denying that Dr. Kuhn remembers reading the relevant warnings. Additionally, it is also worth noting that Dr. Kuhn did not rely on any conversations with Stryker's sales representatives for his use of pain pumps. *Id*. at 17-18 & 63. He also cannot recall how he learned what medicines to use with the pain pumps or how he learned about where to place the catheter for the pain pump. *See id*. at 16-17. What is evident from Dr. Kuhn's deposition is that he relied on his experience and clinical judgment in caring for Plaintiff, not any communication from Stryker, which is within his prerogative as Plaintiff's treating physician.

Given Dr. Kuhn's testimony, Dr. Parisian's opinions about whether those warnings violated FDA regulations are even more irrelevant. In fact, under Tennessee law, there is no "warning causation" when the treating doctor did not rely on the warnings:

> King and Little, as did the plaintiff in Harden, have failed to establish that the defendants' alleged failure to warn was the proximate cause of their injuries. Both of the plaintiffs' implanting physicians were well experienced in the use of internal fixation devices utilizing pedicle screws. Both testified that they relied upon their own knowledge and judgment in deciding to implant the devices into the plaintiffs. The plaintiffs have not shown that these decisions were influenced by any representation which the defendants made or failed to make. Thus, the plaintiffs' claims in this regard fail because they have failed to establish that, had additional warnings been given, the plaintiffs would not have sustained their injuries.

King, 37 S.W.3d at 453 (emphasis added & citations omitted); *see also Cansler v. Grove Mfg. Co.*, 826 F.2d 1507, 1510-11 (6th Cir. 1987) (overturning product liability judgment because plaintiff failed to prove, *inter alia*, that a defect in the warning caused the injury) (applying Tennessee law).

Indeed, this Court has recognized that "[t]he key inquiry" in a warnings case "is whether, 'had additional warnings been given, the plaintiffs would not have sustained their injuries.'" *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010) (Trauger, J.) (quoting *King v. Danek Medical, Inc.*, 37 S.W.3d 429 (Tenn. Ct. App. 2000). Here, without any evidence that Dr. Kuhn would have even read any updated warnings, the answer is no.

B. Dr. Parisian's Allegations of Promotion of "Unapproved Indications" Does Not Impose a Standard of Care Under Tennessee Law.

Dr. Parisian alleges that Stryker "promoted postoperative pain pumps for new and unapproved orthopedic surgery indications." *See* Parisian Rpt. at 5-6. It is true that any alleged off-label promotion would violate federal law. However, Dr. Parisian wrongly implies that this violates the standard of care applicable in this case. Under Tennessee law, the "administrative requirement that a given device be approved by the FDA before being marketed" is merely "a tool to facilitate administration of the underlying regulatory scheme." *King*, 37 S.W.3d at 457 (quoting *Talley v. Danek Medical, Inc.*, 179 F.3d 154 (4th Cir. 1999)). In other words, that FDA requirement "lacks any independent substantive content, it does not impose a standard of care . . . ." *Id.* (quoting *Talley*).

There is no basis for allowing the jury to hear irrelevant "expert" testimony that wrongly excoriates Stryker for allegedly breaking a regulation that does not impose a standard of care under Tennessee law. This type of testimony would only serve to confuse and prejudice the jury, and should not be allowed.

C. Dr. Parisian is an Advocate–Not an Expert–Who Purveys Improper Opinions Regarding Intent, Knowledge, and Causation That are Unconnected to any Regulatory Expertise.

Dr. Parisian has been an expert witness long enough to have developed a *modus operandi* and a reputation. Both are suspect. The former consists of wielding her limited experience with the FDA as a wedge to force open the *Daubert* gate. This purported expertise and testimony flies in the face of *Buckman* and *Daubert*. However, on occasion, Dr. Parisian has made it to the expert chair. If she is allowed, she then morphs into the plaintiff's master story teller and inundates the jury with a far-ranging narrative heavy with speculative claims regarding the intent, knowledge, and actions of defendants and the FDA, but utterly unconnected to her area of claimed expertise. To listen to Dr. Parisian's testimony is to hear the plaintiff's version of events set forth document by document and inference upon inference, and unburdened by foundational knowledge or the narrow boundaries of her experience.

Dr. Parisian "generally takes a collection of facts, imputes motive and knowledge, and draws unsupported conclusions unrelated to any regulatory expertise." *In re Trasylol*, 709 F.Supp. 2d 1347.

> All of Dr. Parisian's opinions suffer from this fatal flaw: she recounts [the medical product's] regulatory history, the contents of [the defendant's] internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory expert analysis.

Id. The last aspect—a lack of analysis that connects the facts to her opinion—has become something of Dr. Parisian's hallmark. In *Trasylol*, the "lack of analysis or connection between the facts and the opinions" was persistent throughout her report and testimony. *Id*. at 1350. In *In re Prempro*, the court characterized her testimony as "a brief overview of some federal regulations, followed by discussion of specific exhibits, largely devoid of regulatory analysis." *In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 571 (8th Cir. 2009) ("*In re Prempro II*") (noting district court's "frustration that she was not linking her testimony to FDA regulations [cited]" and upholding post-trial striking of "much of Dr. Parisian's testimony and related exhibits").

And in *Reece*, the court found it "clear [] that Dr. Parisian seeks to offer testimony and opinions on matters that go well beyond FDA procedures and regulations and her areas of expertise." *Reece v. AstraZeneca Pharmaceutical, LP*, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007).

Dr. Parisian has done the same thing here. For example, after each of Dr. Parisian's opinions, she lists a litany of FDA regulations that Stryker has purportedly violated. Parisian Rpt. at 5-6. But in the remainder of the 65 plus page report, she does nothing besides recount FDA regulations and guidance documents, and lists events in Stryker's regulatory and development history, and scientific research. *Id. generally.* There is literally no effort to tie the stated "violations" with the facts therein. Moreover, Dr. Parisian's opinions are replete with legal conclusions of negligence. This is not proper expert testimony.

Instead of providing the regulatory analysis that is supposed to be her forte, Dr. Parisian routinely offers a factual narrative laden with her personal, unfounded opinion of the alleged misdeeds of the defendant. Indeed, this offering is so typical that "courts have expressed concerns about the use of narrative testimony by Dr. Parisian." *In re Trasylol*, 709 F.Supp. 2d at 1337. In *In re Fosamax*, she had to be specifically prohibited from merely reading from or selectively quoting from the evidence. *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) ("*In re Fosamax*"). *Id.* The *In re Prempro* district court hit upon an apt description of Dr. Parisian's habit in this regard: mere "regurgitation" of the evidence. *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 880 (E.D. Ark. 2008) ("*In re Prempro I*"). On appeal, the Eighth Circuit Court of Appeals upheld the *Prempro* district court's post-trial striking of the majority of Dr. Parisian's testimony because, despite being admonished by the court, Dr. Parisian "often [ ] simply read the contents of exhibits, thus undermining the asserted basis for expert testimony." *In re Prempro II*, 586 F.3d at 571. Indeed, the *In re Trasylol* court ultimately excluded Dr. Parisian entirely pursuant to FRE 702 because of her refusal to perform analysis—she was found to have an utter lack of "'scientific, technical, or other specialized knowledge' that would assist the trier of fact to understand the evidence or to determine a fact in issue." *In re Trasylol*, 709 F.Supp. 2d at 1347.

Here, Dr. Parisian's report foreshadows the testimonial narrative to come. For example, her report's treatment of Stryker's alleged failure to communicate risk of chondrolysis is nothing more than page after page of Stryker's internal documents. Parisian Rpt. at 11-54. There is, characteristically, no attempt to tie this lengthy factual narrative to any sort of expert analysis. It is merely a regurgitation of Stryker documents, pieced together with enough disapproving commentary to create the desired impression of a "bad company." This proffered testimony does not meet the rigors of relevancy under *Daubert* in that it will not assist the trier of fact in understanding or determining a fact in issue—the jury can read the documents and listen to the testimony itself—it does not need Dr. Parisian to do that for them. *See U.S. v. Pollard*, 128 F. Supp. 2d 1104, 1124 (E.D. Tenn. 2001) ("the court must determine whether expert testimony will assist the jury in resolving a question of fact or whether such expert testimony will simply make the job of the jury more difficult").

D. Dr. Parisian's Opinions About What Stryker Should Have Done Differently are Conjecture and Unreliable Because he Failed to Establish Stryker's Knowledge at the Relevant Time.

Of Dr. Parisian's various points, she opines that Stryker "had not studied or tested the safety of post-operative intra-articular continuous infusion with a local anesthetic." Parisian Rpt. at 5-6; *see also id.* at 11-63 *generally.* Dr. Parisian cites to several regulations in support of this alleged failure but these are general propositions to her overall Opinion # 3 only and not specific to this alleged failure. *See id.* at 6 (listing 21 U.S.C. § 331; 21 C.F.R § 812; 21 U.S.C. § 352(f)(1),(2); 21 U.S.C. § 1.21). Dr. Parisian has failed to give any objective, reasonable standard of care for a manufacturer in developing and marketing a pain pump that supports her proposition on Stryker's alleged failure to test. Consequently, Dr. Parisian's opinion is based on her own subjective opinion. This is not expert opinion, as another court just recognized in striking similar testimony by Dr. Parisian. *See Ingram v. Wyeth*, MDL No. 4:03CV01507-WRW (E.D. Ark. September 16, 2010) (in excluding the testimony Drs. Parisian, Blum, and Austin

regarding failure to test stated that "experts cannot simply testify what they believe Defendants could have done versus what they should have done, the "testimony could only be subjective opinion," and is "not expert in nature."), Judge Joe J. Volpe's September 16, 2010 Order, attached as **Exhibit H**.

However, Dr. Parisian should not even examine what Stryker should have done without first determining Stryker's knowledge at the time. Dr. Parisian should be focused on a more basic, relevant question: Stryker's knowledge of the alleged risk at the time of Plaintiff's injury, November 2004.

To determine the liability of a product manufacturer under Tennessee law, the Court should consider the manufacturer's knowledge of the risk:

> In making this determination [whether a product was in a defective condition or unreasonably dangerous], the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable.

TENN. CODE ANN. § 29-28-105(b).

Dr. Parisian offers no evidence that Stryker knew about the alleged risk of use as of November 2004. This Court should reject Dr. Parisian's opinion that is based on a subjective standard and knowledge that was inexistent at the relevant time.

E. Vast Portions of the Subject Matter of Dr. Parisian's Report Lack Chronological Relevance or "Fit."

As is apparently typical of her, Dr. Parisian's Rule 26 report is "broad and unwieldy." *In re Trasylol*, 709 F.Supp. 2d at 1339. It is clearly meant to be a once-and-for-all pronouncement of the alleged regulatory sins of Stryker and, as a result, "discusses events occurring over a wide span of time." *In Re Fosamax*, 645 F. Supp. 2d at 192. Only some of these events are relevant to *this* case. The Court must therefore parse the chronological relevance or "fit" of the subject matter in each paragraph in Dr. Parisian's report relative to the

alleged dates of Plaintiff's surgery and that involved the alleged Stryker pain pump. *Id*. ("Dr. Parisian's report discusses events occurring over a wide span of time. The portions of her testimony relevant in any particular case likely will depend on the dates of the plaintiff's alleged ingestion of Fosamax and onset of ONJ. Thus, transferor courts will have to determine what portions of her testimony fit the facts of the specific cases before them"); *see also U.S. v. Pollard*, 128 F. Supp. 2d at 1116 (citing *U.S. v. Bonds*, 12 F.3d at 555) (the *Daubert* relevance requirement directs that there be a "fit" between the testimony and the issues to be resolved at trial). Consequently, subject matter related to events occurring after that surgery must be excluded as irrelevant. *Id*.; *Osborne v. Pinsonneault*, 2009 WL 1046008 at *5 (W.D. Ky. Apr. 20, 2009) (conduct after alleged negligent event has no bearing on negligence claims), attached as **Exhibit I**.

Here, plaintiff's surgery occurred on November 15, 2004. Therefore, any subject matter in Dr. Parisian's report regarding events that occurred after this date is irrelevant and should be excluded. *In Re Fosamax*, 645 F. Supp. 2d at 192; *Osborne*, 2009 WL 1046008 at *5. Such subject matter falls into three categories: (1) Stryker's conduct, post-marketing; (2) Stryker's interaction with the FDA; and (3) publication of scientific hypothesis and literature.

Dr. Parsian's report is replete with events, as the basis for her opinion, that post-date Plaintiff's alleged injury in this case. For example, beginning at page 6 through 8 and then later at page 53, Dr. Parisian's report discusses FDA alerts and guidance documents related to general device and infusion pumps generally which were issued 6 years after Plaintiff's surgery. Further, the last 10 pages of Dr. Parisian's report purports to discuss scientific literature that discusses risk factors for cartilage. *Id*. at 54-65. Many of the articles, specifically all of the human clinical data, however, were published after Plaintiff's date of surgery. As such, they could have no bearing on Stryker's conduct prior to that surgery and are therefore irrelevant.

Finally, the remainder of Dr. Parisian's report spends a tremendous amount of space listing Stryker's post-marketing conduct. *Id*. at 25-53. The entire discussion commences from February 2005, and proceeds forward chronologically all the way to May 11, 2009. *Id*.

Not a single paragraph of this is relevant, because it all involves events that occurred months or years after Plaintiff's surgery. The only potential exceptions are Paragraphs 124, 134 and 135, in which Dr. Parisian reports Don Kelley's vague, partial memory of a conversation with Dr. Paulos that might have happened, if at all, in 2003. *Id*. at 36-39. This speculative testimony is without foundation, particularly considering that Dr. Paulos has no memory of such a conversation. *See* Deposition of Lonnie Paulos, M.D. taken at Gulf Breeze, Florida, on August 15, 2008 at 31:9-20, selected pages attached as **Exhibit J**. As a result, the subject matter of those paragraphs should also be excluded for irrelevance or lack of chronological "fit." *See U.S. v. Pollard*, 128 F. Supp. 2d at 1116; *In Re Fosamax*, 645 F. Supp. 2d at 192; *Osborne*, 2009 WL 1046008 at *5.

F. Dr. Parisian has No Personal Knowledge or Qualifications to Offer Opinions on Stryker's Purported Regulatory Violations.

Further, Dr. Parisian has no personal knowledge or factual basis to opine that the FDA-approved labeling for Stryker's pain pump at issue should have contained different language on use and warnings. The appropriate party to opine about the scope of the FDA's approval is the FDA itself. Another court battling similar testimony offered by Dr. Parisian, agreed:

> Dr. Parisian's opinion on what the FDA did and did not approve does not meet Rule 104 foundational requirements because she lacks personal knowledge on that subject. The proper person that could testify as to what the FDA did and did not approve . . . based on Guidant's submissions to the FDA would be the person responsible for approving the [device].

See In re Guidant Corp., 2007 WL 1964337 at *15 (ordering that "Dr. Parisian also shall not be permitted to render an opinion on whether Guidant 'violated' . . . the federal Food, Drug, and Cosmetic Act"). Here, Dr. Parisian did not speak to any of the experts at the FDA who reviewed

Stryker's pain pump 510(k) applications or the post-marketing surveillance. June 4, 2010 Parisian deposition at 32:15-20.

Dr. Parisian is not qualified to offer an opinion contrary to the plain wording of the labeling cleared by the FDA. During her brief tenure at the FDA, Dr. Parisian does not recall being part of the review process for pain pumps and has no experience in the development or approval of the indications and labeling for pain pumps outside of the litigation context. March 2, 2009 *Grossnickle* trial at 924:21-24, selected pages attached as **Exhibit K**. Dr. Parisian was not even in the division that had responsibility over orthopedic devices during her time there. *Id.* at 925:24-926:8.

G. Any Opinion on Causation by Dr. Parisian Lacks Reliability and Foundation.

It appears that Dr. Parisian also plans to opine on causation as to Plaintiff's alleged injury, which she has tried to do before in this litigation. Specifically, she discusses the evolution of research in the scientific community as to chrondolysis, plaintiff's alleged injury. However, the report contains absolutely no reference to the plaintiff herein—Dr. Parisian has no foundation from which to connect her historical narrative to the cause of plaintiff's alleged injuries.

In order to prove causation on a strict liability theory, Plaintiff must prove that Stryker's conduct was a "substantial factor" in causing her alleged injuries. *Davis v. Komatsu Am. Indus. Corp.*, 46 F. Supp. 2d 745, 751 (W.D. Tenn. 1999) *rev'd in part on other grounds*, 2001 WL 1042229 (6th Cir. 2010). Alternatively, causation in negligence requires proof "that some action within the defendant's power more probably than not would have prevented the [alleged] injury." *Pittman v. Upjohn Co.*, 890 S.W. 2d 425, 428 (Tenn. 1994). Dr. Parisian's

historical narrative does not connect the dots to satisfy Plaintiff's general or specific causation burden, especially given Dr. Kuhn's testimony outlined above.

Additionally, Dr. Parisian, by her admissions, is not an orthopedic surgeon or a surgeon of any kind for that matter. March 2, 2009 *Grossnickle* Trial at 897:5-8. Dr. Parisian is also not an anesthesiologist or epidemiologist. While having a medical degree, she has not been in the clinical setting, treating patients, for 20 years. *Id*. at 894:21-895:1. And 20 years ago, all her clinical experience amounted to was a brief stent in an emergency room setting. The expertise that she brings to the table is a background in pathology and her 4 years at the FDA in departments where she performed no work on pain pumps or side effects alleged from their use.

As expected with her vast experience as an expert, Dr. Parisian has offered causation opinion testimony before. One such case, *Reece v. Astrazeneca*, the court found that her opinions on medical causation were derived solely for the purposes of the litigation and that she did not have any outside expertise in the area. 500 F.Supp.2d at 745-746 ("Dr. Parisian's opinions were developed solely for purposes of testifying at the trial of plaintiff's claims . . . [a]s such, Dr. Parisian's testimony is not reliable and will not assist the trier of fact in understanding and disposing of the issues." Similarly in *this* case, Dr. Parisian does not have the foundation or qualification to opine—she should not be allowed to testify under Rule 702 as to her proffered testimony on the alleged causation of chrondolysis with the use of Stryker's pain pump.

H. Dr. Parisian Will Not Limit Her Testimony to Facts Within Her Knowledge and Opinions Within Her Expertise.

Given the plethora of legal opinions taking her to task, Dr. Parisian's manifold shortcomings are no secret. Nevertheless, courts have occasionally allowed her to testify anyway under strict standards, despite "grave reservations as to the exact substance of [her] proposed testimony." *In Re Human Tissue Prods. Liab. Litig.*, 583 F. Supp. 2d 644, 666-67 (D.N.J. 2008). However, Dr. Parisian has proven uncontrollable. Indeed, "[i]n the past, courts

have had trouble limiting Dr. Parisian's testimony, despite her and the plaintiffs' assurance that she would not exceed its proper scope." *In re Trasylol*, 709 F.Supp. 2d at 1345 n. 29. The *In re Prempro* case, as recounted by the *In re Trasylol* court, provides a typical example. There,

> the judge outlined the permissible testimony pretrial but came across substantial problems with Dr. Parisian's testimony during trial. More specifically, the plaintiff asserted, as Plaintiffs here assert, that Dr. Parisian would opine about the information that the FDA requires and whether or not the defendant-company's response was appropriate under FDA guidelines. However, Dr. Parisian simply summarized documents without referencing FDA requirements or providing any expert analysis . . . . Despite repeated sidebar conferences, Dr. Parisian continued to read lengthy passages from exhibits, offered testimony beyond her expert report, and failed to limit her testimony to any FDA regulations.

Id. at 1339 (citations omitted). This incorrigible recalcitrance has recently led one court to recognize Dr. Parisian's inability or refusal to change her stripes and foreclose her gambit entirely by excluding her as unreliable and unhelpful:

> Plainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon inference in order to offer her 'takeaway' or 'take home message' with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury.

Id. at 1351. This Court should do likewise.

V. CONCLUSION

On the basis of the foregoing, Stryker submits that Dr. Parisian's proposed expert testimony is wholly inadmissible and she should therefore be excluded under Rule 702 and *Daubert*.

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Respectfully submitted,

By: */s/ Gene M. Williamss*

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CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of November, 2010, I electronically transmitted the foregoing document to the Clerk of the court using the ECF system for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

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